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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,819	12/21/2001	Colleen E. Hayes	NLIGHTS-06903	6475

7590 07/29/2003
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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/29/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,819

Applicant(s)

HAYES ET AL.

Examiner

Sabiha Qazi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 21-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 21-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

OFFICE ACTION ON MERITS

Acknowledgement is made of the response file in paper no. 9. Amendments are entered. Claims 21-44 are pending. No claim is allowed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The arguments filed by applicants were fully considered but are found persuasive in-part therefore the double patenting rejection is withdrawn, the arguments regarding rejection under 103 (a) are not found persuasive therefore rejection is maintained for the

Claims 21-44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Snowden (US Patent 6,214,373). The reference teaches a nutritional composition of vitamin D and method for treating inflammatory bowel disease such as Crohn's disease or ulcerative colitis, which embraces instantly, claimed invention. See the entire document especially lines 59-65, col. 1; lines 27-59, col. 2; lines 9-54, col. 4; lines 1-30, col. 5; Tables 1 and 2 and claims.

Instant claims differ from the reference in claiming the method of use of specific vitamin D compounds, vitamin D2 and 19-nor vitamin D3 whereas prior art teaches any vitamin D compound. Example of the instant invention and prior art teach 1alpha, 25 hydroxy vitamin D3.

Claim Rejections - 35 USC § 103

Claims 21-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Neef et al. US Patent 5,446,035. See the entire document especially lines 34 and 35 in col. 6; lines 15-31.

Instant claims differ from the reference in claiming few specific compounds for the treatment of inflammatory bowel diseases wherein prior art teaches a broader range of vitamin D compounds which are potent vitamin D receptor antagonists, and may be useful for inflammatory disorders like arthritis, colitis ulcerosa and ileitis terminalis.

It would have obvious to one skilled in the art at the time of invention to prepare vitamin D derivatives for use as anti-inflammatory agent for the treatment of inflammatory bowel disease as presently claimed. There is a motivation provided by the prior art that these compounds may be useful for the treatment of colitis ulcerosa. The expectation is due to the teaching that these compounds are potent vitamin D receptor antagonists.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 703-305-3910.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be

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reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



S. QAZI, PH.D
PRIMARY EXAMINER

July 28, 2003